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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/305,084	05/04/1999	Robert J. Schneider	5914-080-999	1583

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PENNIE & EDMONDS LLP  
1667 K STREET NW  
SUITE 1000  
WASHINGTON, DC 20006

EXAMINER

HARRIS, ALANA M

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 06/04/2002

14

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/305,084

Applicant(s)

SCHNEIDER ET AL.

Examiner

Alana M. Harris, Ph.D.

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 March 2002.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-5, 14 and 15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5, 14 and 15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

**DETAILED ACTION**

***Response to Amendment***

1. Claims 1-5, 14 and 15 are pending.  
Claims 1, 14 and 15 have been amended.  
Claims 1-5, 14 and 15 examined on the merits.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Drawings***

3. The drawings submitted March 5, 2002 as Paper number 13 were approved by the draftsman. Accordingly, the objection to the drawings is withdrawn.

***Withdrawn Rejections***

***Claim Rejections - 35 USC § 112***

4. The rejection of claims 1-5, 14 and 15 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in light of Applicants' arguments.

***Withdrawn Rejections***

***Claim Rejections - 35 U.S.C. § 112***

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5. The rejection of claim 25 under 35 U.S.C. § 112, first paragraph, as failing to provide an adequate written description of the invention and failing to provide an enabling disclosure without complete evidence either that the claimed biological materials are known and readily available to the public or complete evidence of the deposit of the biological materials is withdrawn in light of Applicants' amendment to the specification.

***New Grounds of Rejection and Maintained Rejections***

***Claim Rejections - 35 USC § 112***

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-5, 14 and 15 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The written description in this case only sets forth selective endothelin B subtype (ETB) antagonist, BQ788, which is implemented in Example 1, page 48 of the specification. Applicants are not in possession of all selective ETB antagonists, which may or may not include for example IRL-1038, H-3596 or mimics of the ETB antagonist compounds see page 25, lines 11-25.

*Vas-Cath Inc. V. Mahurkar*, 19 USPQ2d 1111, clearly states that “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the ‘written description’ inquiry, *whatever is now claimed*.” (See page 1117). The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.” (See *Vas-Cath* at page 1116). Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 USC 112 is severable from its enablement provision (see page 115).

Applicants broadly claim methods of treating cancer utilizing ETB antagonists. However, Applicants are not entitled, nor is the specification enabled for the use of all ETB antagonists capable of playing a role in preventing the downregulation of E-cadherin in a cancer cell or in the cascade leading to the early developments associated with melanoma development. Applicant is only in possession of one species, which is not identified by a sequence identity number or defined by structure. Applicants are not permitted to claim all selective ETB antagonists and mimics thereof that are encompassed by the claims, hence not entitled to the wide breadth of the claims at issue. There is no description of the variability in the structure or binding affinity of compounds that bind the ETB receptor that may be tolerated and no information regarding the relation of structure to function. Structural features that could distinguish the compounds in the genus from others excluded are missing from the disclosure.

This is insufficient to support the generic claims as provided by the Interim Written Description Guidelines published in the June 15, 1998 Federal Register at Volume 63, Number 114, pages 32639-32645.

***Claim Rejections - 35 USC § 102***

8. Claims 1-4 and 14 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Number 6,063,911 (filed December 22, 1998) is maintained and made. Applicants have amended claim 14 to specify that the compound used in the claimed method is a selective antagonist of the endothelin B receptor and that this amendment should render the claim free of the art. This is not found persuasive.

Applicants' specification does not define selective antagonists of endothelin B receptor. The specification does not set forth parameters governing what is to preclude molecules that bind endothelin B receptor or what limitations would characterize a selective antagonist. In view of the fact the specification is silent on the term selective antagonists of endothelin antagonist and the claims given the broadest interpretation the rejection stands and instated. U.S. Patent #6,063,911 continues to anticipate claim 14, as well as claims 1-4 due to the fact the patent discloses an endothelin antagonist that can be used in a method for treating cancer, particularly melanoma (column 3, lines 19-44) and for the reasons of record. Inherently, this disclosed compound would mimic Endothelin-1.

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9. Claims 1, 4 and 14 rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Number 5,382,569 (January 17, 1995/ Reference AP on IDS). U.S. Patent #5,382,569 discloses novel antagonists of endothelin that are antagonists to an ETB, which are useful in treating cancer (column 1, lines 10-26). These antagonists also mimic endothelin-1, see the abstract.


10. Claims 5 and 15 are free of the art.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (703) 306-5880. The examiner can normally be reached on 6:30 am to 4:00 pm, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can be reached on (703) 308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4315 for regular communications and (703) 308-4315 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Alana M. Harris, Ph.D.  
June 2, 2002

  
ANTHONY C. CAPUTA  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600